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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
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| MORRIS, PATRICIA L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1625 | |

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/796,466 | BRENDEL ET AL. | |
| | Examiner | Art Unit | |
| | Patricia L. Morris | 1625 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *5 and 6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-4 and 7 are under consideration in this application.

Claims 5 and 6 remain held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

### *Election/Restriction*

The restriction requirement is deemed sound and proper and is hereby made FINAL.

This application contains claims 5 and 6 drawn to an invention nonelected with traverse in the reply filed March 8, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 7 are rejected under 35 U.S.C. 102(a), (b) and/or (e) as being anticipated by Brendel et al. I (WO 02/088073), II (US 2003/0197033) for the reasons set forth in the previous Office action.

Again, Brendel et al. I, II teach the process of preparing and the compound by a structural formula (example 137) which embraces the S- and R-configuration. Note general method 6 of Brendel et al. I, II. Brendel et al. II teach that the invention relates to the use of all possible stereoisomers. Note section [0163] of Brendel et al. II. Hence, each of the isomers having the same use are deemed to be anticipated by the references.

Contra to applicants' arguments in the instant response filed July 25, 2005, where a reference describes a sufficiently limited genus of a number of compounds closely related to another in structure, the reference may be said to provide a description of those compounds just as if they were identified in the reference by name. In re Schaumann, 572 F.2d 312, 197 USPQ 5 (CCPA 1978). Section [0163] of Brendel II states that the invention includes all the separated or mixed forms of the diastereomers and enantiomers. Accordingly, in the instant case, since the formula having asymmetric carbons is taught, one merely has to select from the possible isomers to arrive at the claimed invention.

The factual situation here is well within the "Petering doctrine": In re Petering et al., 49 CCPA 993, 301 F.2d 676, 133 USPQ 275 (1962). There the court affirmed a 102(b) rejection on the ground that the prior art, while it did not expressly name applicants' claimed compounds, did describe such a limited class of only twenty compounds "that one skilled in this art would at once envisage each member of this limited class, even though this skilled person might not at once define in his mind the formal boundaries of the class as we have done here" (133 USPQ at

280). Here we do not have anywhere near twenty possible compounds within the limited class described by the references.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brendel et al. I, II for the reasons set forth in the previous Office action.

Again, Brendel et al. I,II teach the racemate which includes the claimed compound having the same use. Brendel et al. II teach that the invention includes all the isomers and the individual sterisomers can be effected, if desired, by a separation of the mixture by conventional means. Note section [0163] therein. Hence, the claimed particular isomer as well as its relative selectivity of properties *vis-à-vis* the racemate are suggested by the references.

Applicants appear to argue that one having ordinary skill in the art would not have been motivated to produce the compounds encompassed by the claims. The motivation is not abstract but is always related to the properties or uses that one having ordinary skill in the art would have expected the resulting compound to exhibit. In situations involving chemical compounds bearing a close structural similarity, the requisite motivation stems from the expectation that compounds exhibiting closely similar structures will exhibit similar properties. In the situation here, one would not have to modify the disclosure of Brendel et al. I, II, but merely employ compounds that are generically embraced in a narrow manner by the disclosed formula of

As previously discussed, the requisite motivation for producing the claimed compounds stems from the fact that they are generically disclosed. Therefore, one having ordinary skill in the art would have found it prima facie obvious to select any on the compounds embraced by the generic formula, including those of the claims, with the expectation that each of them can be used for the treatment and prevention of cardiac and superventricular arrythmias or atrial flutters.

The data in the specification is of little if any probative value because it fails to show any unexpected or unobvious results. With respect to one isomer being essentially inactive, it will be seen that in the third paragraph from the end of In re Adamson, 125 USPQ 133, the court states that the affidavit therein shows the laevo-isomer to be about twice as active as the racemate and the dextro-isomer to be virtually inactive, as antispasmodics. The court found that the prior art reasonably suggested the result shown in the affidavit. In the penultimate paragraph of the decision, the court comments that "in establishing that fact experimentally, applicants have done no more than is suggested by the prior art and have ascertained no more than what would be expected by one skilled in the art, i.e., the activities are different.

***Claim Rejections - 35 USC ∋ 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of cardiac arrhythmias, supraventricular arrhythmias, atrial fibrillation or atrial flutters, does not reasonably provide enablement for the prevention of these

arrhythmias and flutters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

***The nature of the invention***

The nature of the invention is the instant compound and the corresponding compositions and the use of this combination for the treatment and prevention of cardiac arrhythmias, of supraventricular arrhythmias, of atrial fibrillation or atrial flutters..

***State of the Prior Art***

The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activites (i.e,, what compounds can prevent which specific disease. There is no absolute predictability even in view of the seeming high level of skill in the art. The existence of these obstacles established that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any preventive regimen on its face.

***The amount of direction or guidance and the presence or absence of working examples***

Again. the specification is silent as to whether the compound of claim 1 prevents any of the recited arrhythmias.

***The breadth of the claims***

The breadth of the claims are drawn to the specific compound in addition to the pharmaceutical compositions and the method of preventing all the above noted arrhythmias and atrial flutters.

***The quantity of experimentation needed***

The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to the compounds and pharmaceuticals compositions. Contra to applicants arguments in the instant response, applicants have failed to show that the instant compound and all the possible salts thereof, ***prevent*** all the above noted arrhythmias and all atrial flutters.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. Applicants are referred to In re Fouche, 169 USPQ 429 CCPA 1971, MPEP 716.02(b). Applicants are also referred to In re Wands, 858 f.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte Foreman, 230 USPQ 546 (Bd. Of App. and Inter 1986).

In terms of the 8 Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of unpredictability in the art of the invention, and the poor amount of direction provided by

applicants. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Again, the term preparation in claim 4 is indefinite to its meaning. Do applicants intend a composition? Again, the term preparation fails to define a composition.

Again, claim 4 provides for the use of treating humans or for veterinary use, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Again, claim 4 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Contra to applicants' arguments, use limitations in the claim are not proper. In order to overcome this rejection, the use limitations must be deleted.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 8, 10-14 and 19-24 of copending Application No. 10/132,163 for the reasons clearly set forth in the record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the racemate of the instant compound is claimed therein having the same use. Hence, patentable distinction is not seen because the skilled artisan would obviously realize that in view of the asymmetric carbon in the compound that compounds of this structure would be a racemate composed of equal amounts of optically active antipodes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants have failed to proffer a terminal disclaimer. Thus, this rejection is maintained.

***Conclusion***

No claim is allowed.

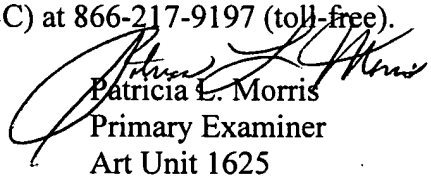
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris
Primary Examiner
Art Unit 1625

plm
September 16, 2005